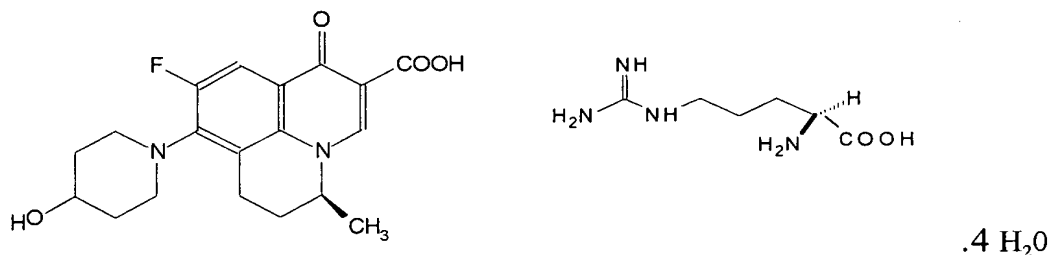**IN THE CLAIMS**

1. (Original) S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-

1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate of the formula I

.4 H₂0

Formula I

in a crystalline form.

2. (Original) A S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,

5H-benzo [i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate having the following

X-ray powder diffraction data: (2θ):4.86± 0.2,14.10 ± 0.2, 14.90 ± 0.2, 19.35 ± 0.2, 22.20 ±

0.2, 23.04 ± 0.2, 23.54 ± 0.2, 28.44 ± 0.2, 39.44 ± 0.2.

3. (Original) A S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,

5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate having the following

X-ray powder diffraction data: (2θ):4.86± 0.2,14.10 ± 0.2, 14.90 ± 0.2, 19.35 ± 0.2, 22.20 ±

0.2, 23.04 ± 0.2, 23.54 ± 0.2, 28.44 ± 0.2, 39.44 ± 0.2.; a DSC exotherm at 194. 93°C (onset

at 189.42°C) and one endotherm at 87.83°C, 144.03°C and 251.26°C and a water content of

between 11.0 to 12.5% by weight as determined by titration according to Karl Fischer.

4. (Original) The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-

1H, 5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to

claim 2, having a DSC exotherm at 194.93°C (onset at 189.42°C) and one endotherm at 87.83°C, 144.03°C and 251.26°C.

5. (Original) The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, wherein the solubility in a solution of pH 9.5 is 5.0 mg/ml.

6. (Original) The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3, wherein the solubility in a solution of pH 9.5 is 5.0 mg/ml.

7. (Original) The S-(-)-9- fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1, wherein the water content is between 11.0 % and 12.5 % by weight as determined by titration according to Karl Fischer.

8. (Original) The S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo [i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2, wherein the water content is between 11.0 % and 12.5 % by weight as determined by titration according to Karl Fischer.

9. (Original) A process for the manufacture of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate comprising the steps of:

    a) heating a suspension of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j]quinolizine-

2-carboxylic acid L-arginine salt tetrahydrate in an organic solvent and water at 70-80°C to obtain a clear solution;

  b) cooling the solution to provide a crystalline substance;

  c) isolating the crystalline form of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H, 5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate at 30°C - 35°C by filtration or centrifugation;

  d) air drying of the crystalline form of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate at a temperature between 30°C - 35°C.

10. (Original) A process according to claim 9, wherein the organic solvent is acetone or acetonitrile.

11. (Original) The process according to claim 9 wherein the organic solvent is acetone.

12. (Original) A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 and a carrier, diluent, solvent or excipient.

13. (Original) A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 and a carrier, diluent, solvent or excipient.

14. (Original)   A composition comprising S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate tetrahydrate according to claim 3 and a carrier, diluent, solvent or excipient.

15. (currently amended)   A method for treating a disease caused by a ~~microbial~~ <u>bacterial</u> infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 to the mammal in need thereof.

16. (currently amended)   A method for treating a disease caused by a ~~microbial~~ <u>bacterial</u> infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 to the mammal in need thereof.

17. (currently amended)   A method for treating a disease caused by a ~~microbial~~ <u>bacterial</u> infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3 to the mammal in need thereof.

18. (currently amended)   A method for preventing a disease caused by a ~~microbial~~ <u>bacterial</u> infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]

5

quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 to the mammal at risk of being infected.

19. (currently amended)   A method for preventing a disease caused by a ~~microbial~~ bacterial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 to the mammal at risk of being infected.

20. (Currently amended)   A method for preventing a disease caused by a bacterial ~~microbial~~ infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j] quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3 to the mammal at risk of being infected.

21. (new)   A method for treating a bacterial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 1 to the mammal in need thereof.

22. (new)   A method for treating a bacterial infection in a mammal comprising administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 2 to the mammal in need thereof.

23. (new)   A method for treating a bacterial infection in a mammal comprising

administering an effective amount of S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid L-arginine salt tetrahydrate according to claim 3 to the mammal in need thereof.

24. (new)   The method according to claim 15, wherein the disease is impetigo, pneumonia, bronchitis, pharyngitis, endocarditis, urinary tract infection, gastro-intestinal infection or bacteremia.

25. (new)   The method according to claim 16, wherein the disease is impetigo, pneumonia, bronchitis, pharyngitis, endocarditis, urinary tract infection, gastro-intestinal infection or bacteremia.

26. (new)   The method according to claim 17, wherein the disease is impetigo, pneumonia, bronchitis, pharyngitis, endocarditis, urinary tract infection, gastro-intestinal infection or bacteremia.

27. (new)   The method according to claim 18, wherein the disease is impetigo, pneumonia, bronchitis, pharyngitis, endocarditis, urinary tract infection, gastro-intestinal infection or bacteremia.

28. (new)   The method according to claim 19, wherein the disease is impetigo, pneumonia, bronchitis, pharyngitis, endocarditis, urinary tract infection, gastro-intestinal infection or bacteremia.

29 (new)   The method according to claim 20, wherein the disease is impetigo, pneumonia, bronchitis, pharyngitis, endocarditis, urinary tract infection, gastro-intestinal

infection or bacteremia.

30. (new)   The method according to claim 15, wherein the disease is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense* , *E.coli, Klebsiella, Proteus, Serratia, Citrobacter,* and *Pseudomonas*.

31. (new)   The method according to claim 16, wherein the disease is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense* , *E.coli, Klebsiella, Proteus, Serratia, Citrobacter,* and *Pseudomonas*.

32. (new)   The method according to claim 17, wherein the disease is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense* , *E.coli, Klebsiella, Proteus, Serratia, Citrobacter,* and *Pseudomonas*.

33. (new)   The method according to claim 18, wherein the disease is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter*, and *Pseudomonas*.

34. (new)   The method according to claim 19, wherein the disease is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter*, and *Pseudomonas*.

35. (new)   The method according to claim 20, wherein the disease is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative *Staphylococci*, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of *Streptococci*, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium, Chryseobacterium meningosepticum, Chryseobacterium indologense , E.coli, Klebsiella, Proteus, Serratia, Citrobacter*, and *Pseudomonas*.

36. (new)   The method according to claim 21, wherein the infection is caused by bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative

Staphylococci, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase

negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of

Streptococci, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium,*

Chryseobacterium meningosepticum, Chryseobacterium indologense , *E.coli, Klebsiella,*

Proteus, Serratia, Citrobacter, and *Pseudomonas.*

37. (new)   The method according to claim 22, wherein the infection is caused by

bacteria selected from the group consisting of *Staphylococcus aureus*, coagulase negative

Staphylococci, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase

negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of

Streptococci, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium,*

Chryseobacterium meningosepticum, Chryseobacterium indologense , *E.coli, Klebsiella,*

Proteus, Serratia, Citrobacter, and *Pseudomonas.*

38. (new)   The method according to claim 23, wherein the infection is caused by bacteria

selected from the group consisting of *Staphylococcus aureus*, coagulase negative

Staphylococci, methicillin-resitant *Staphylococcus aureus*, methicillin-resistant coagulase

negative *Staphylococci*, *Enterococci*, beta-haemolytic *Streptococci*, viridans group of

Streptococci, multi-drug resistant *M. tuberculosis, M. intracellulare, M. avium,*

Chryseobacterium meningosepticum, Chryseobacterium indologense , *E.coli, Klebsiella,*

Proteus, Serratia, Citrobacter, and *Pseudomonas.*